UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CORY HANKS, on behalf of himself and all others similarly situated,	)	
Plaintiff,	)	CIVIL ACTION NO.:
vs.	)	
DAVOL, INC., and C.R. BARD, INC.	)	
Defendants.	)	

CLASS ACTION COMPLAINT AND JURY DEMAND

Plaintiff, Cory Hanks, by and through his attorneys, brings this action individually and on behalf of all others similarly situated, and for their Class Action Complaint (hereinafter "Complaint"), alleges the following upon information and belief:

NATURE OF THE ACTION

1. Plaintiff brings this action on behalf of himself and the Class defined herein against C.R. Bard, Inc. (hereinafter "Bard") and its wholly owned subsidiary, Davol, Inc., (hereinafter "Davol"), for their sale and distribution of defective Composix Kugel Mesh Patches. The Defendants' defective product has been surgically implanted into the body of the Plaintiff and the class members. The patch presents, and will continue to present, a substantial risk of injury or death to the Plaintiff and the Class Members. As a result, Plaintiff and the Class have been injured and will need continual and ongoing medical monitoring.

PARTIES

2. Plaintiff Cory Hanks ("Cory") is an individual citizen and resident of the State of Massachusetts. During the relevant time period, Cory had hernia repair surgery which included the implantation of a Composix Kugel Mesh Patch into his body. That patch remains in his body

to date. Cory Hanks meets the definition of a class member set forth in this Complaint.

3. Defendant Davol Inc. (hereinafter "Davol") is and was a wholly owned subsidiary of Bard, with its principal place of business at 100 Sockanosset Crossroads, P.O. Box 8500, Cranston, Rhode Island, 02920. At all times relevant, Davol was a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business for manufacturing hernia surgical repair products in Cranston, Rhode Island. Davol designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the State of Massachusetts.

4. Defendant Bard is a New Jersey corporation with its principal office and place of business at 730 Central Avenue, Murray Hill, New Jersey, 07974, and at all times relevant designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the State of Massachusetts.

JURISDICTION AND VENUE

5. This Court has diversity jurisdiction over the Class pursuant to 28 U.S.C. §§ 1332(d)(2) and (6) of the Class Action Fairness Act of 2005. Plaintiff and each member of the putative Class have suffered aggregate damages exceeding five million dollars ($5,000,000), exclusive of interest and costs. There are members of the Class who are citizens of a different State than Defendants.

6. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a) because Plaintiff resides in this judicial district. Also, a substantial part of the events giving rise to the claims at issue arose in this district.

FACTUAL BACKGROUND

7. This class action involves the Composix Kugel Mesh Patch manufactured by Defendants between 2001 and January 2007. These Composix Kugel Mesh Patches were sold by Defendants for implantation in patients in the course of hernia repair surgery.

8. Upon information and belief, from 2004-2006 alone, Defendants had sales from their Surgical Specialties segment of business, which includes the Composix Kugel Mesh Patch, of roughly one billion dollars ($1,000,000,000).

9. A hernia is a protrusion of an organ or tissue through an abnormal opening in the body. Hernias occur when a piece of intestine slips through a weakness in the abdominal wall, creating a bulge you can see and feel. Hernias can develop around the navel, in the groin or any place where you may have had a surgical incision.

10. The Composix Kugel Mesh Patch was designed to fix the hernia by placing the patch on the inside of the abdominal wall, and therefore, the pressures of the body help to hold the patch in place over the hernia defect.

11. The Kugel Mesh line of products, invented by Dr. Robert D. Kugel, was first manufactured by Surgical Sense, Inc., starting in or around 1996. In January of 2000, Bard acquired the Kugel line of hernia repair products from Surgical Sense, Inc.

12. Defendants submitted their 510K Application for approval of the Composix Kugel Mesh Patch to the Federal Drug Administration (the "FDA") on January 22, 2001.

Following the 510K Application, the patch was authorized by the FDA as a Class II medical device. Shortly thereafter, in 2001, Bard introduced the Composix Kugel Mesh Patch to the market through its wholly-owned subsidiary, Davol.

13. The Composix Kugel Mesh Patch is a two sided "dual mesh" prosthetic device developed to repair ventral (hernias of the abdominal region) and incisional hernias and was indicated by Defendants as an alternative to inguinal hernia repairs as well. The Composix Kugel Mesh Patch is inserted behind the hernia defect in the abdomen through a small incision. In order to fit through the small incision the mesh is folded in half. Once inside the abdomen the mesh re-deploys as a result of a hard "memory recoil ring" (or "PET coil ring") that surrounds the mesh.

14. The two sides of the Composix Kugel Mesh Patch are composed of two very different materials; with two very different purposes. Basically, the patch has a 'sticky' side and a 'slick' side. The sticky side is designed to face the abdominal wall and is composed of a double layer of Marlex™(monofilament polypropylene or PPM). This fabric has a very high tissue ingrowth factor - essentially making it like an adhesive. The 'slick' side of the patch is intended to face the bowels and is composed of expanded Teflon (ePTFE). This expanded Teflon fabric has a very low tissue ingrowth factor and is designed to shield the soft tissue of the bowels and other organs from the "sticky" Marlex™ side of the Patch.

15. The inherently adhesive qualities of the Marlex side of the Composix Kugel Mesh Patch make it imperative that it never comes in contact with the bowels and other organs.

16. Due to the design and/or manufacturing defects present, this can occur when the mesh folds over on itself, the mesh wrinkles during placement or the mesh pulls away from the abdominal wall allowing bowel to loop and adhere to the 'sticky' side.

17. As a result, the mesh can: adhere (through tissue ingrowth) to vital organs and intestines; twist around the bowels and organs and cause strangulation and/or serious obstructions; cause necrosis of the organ tissue; become impossible to remove without also removing large portions of the bowel; develop infections; and lead to peritonitis, sepsis, organ shutdown and even death.

18. The plastic 'memory recoil' ring in the Composix Kugel Mesh Patch was intended as a way to maintain integrity of the shape of the patch, and in doing so, keep the 'sticky' side (Marlex™/PPM side) away from the sensitive organs and intestines.

19. Due to the design and/or manufacturing defects the memory recoil ring is prone to failure in several ways, including: pulling apart at the weld; breaking away from the weld; kinking, buckling, bending and folding directly across from the weld; and separating or tearing from patch material.

20. On information and belief, these defects and/or others were caused by multiple design and manufacturing errors and oversights, including but not limited to: failing to properly test the weld strength of the rings; failing to run strength tests on the larger size rings; sewing lines damaging the ring during the manufacturing process and causing it to splinter or fracture; mesh shifting during sewing resulting in a 'shrunken' pocket causing the ring to buckle; the weld joint being placed at an incorrect location in the patch; and poor design and technique instruction by Defendants causing the physicians' staples and/or sutures to damage the ring during placement.

21. When the memory recoil ring malfunctions, numerous serious problems can occur, including:

a. the sharp/fractured PET plastic of the memory recoil ring can pierce the bowels or organs;

b. the ring can force its way through the abdominal wall and skin;

c. the ring can bend or break within the patch, causing it to lose its shape and forcing the "sticky" side onto the bowels and organs;

d. the ring can kink opposite the weld, pulling the patch away from the abdominal walls allowing the bowel to loop up and onto the "sticky" side; and

e. the ring can slide upon itself within the patch, pulling the patch into a ball or causing it to pull away from the abdominal wall.

f. the ring and/or the patch can otherwise fail to perform as intended, represented and/or designed.

22. The resulting injuries and damages from this ring failure include: fistulae created by the perforation of the bowels and other organs; perforation of the abdominal wall and skin; internal bleeding and necrosis of tissue; strangulation and/or serious obstructions of the bowels and organs; recurrence of hernias and prolonged hospitalizations; the necessity of removing large portions of the bowel; infections; and can lead to peritonitis, sepsis, organ shutdown, and even death.

23. Immediately after the Composix Kugel Mesh Patches were placed on the market, Defendants began receiving actual notices of memory ring failures as well as injuries stemming from Composix Kugel Mesh Patch defects.

24. Defendants actively and intentionally concealed this notice of the defective and dangerous condition associated with the Composix Kugel Mesh Patches from Plaintiff, Plaintiff's physicians, the FDA, members of the Class and the general public.

25. No later than 2003, Defendants uncovered serious problems with the weld process involving the memory recoil ring.

26. Despite attempts to correct the problem at the plant, Defendants found the

corrective measures to be ineffective and the process still not in control.

27. Defendants were aware that these weld issues had existed from the time the Kugel Patches were originally placed on the market and all current lots suffered from this dangerous defect. Even the little information disclosed to date was intentionally withheld from Plaintiff, Plaintiff's physicians, members of the Class, the FDA, and all other individuals who had been implanted or would be implanted with Composix Kugel Mesh Patches using the memory recoil ring.

28. As early as 2002, but after the defective and dangerous patch was already placed on the market, Defendants conducted physician screenings and reviews.

29. An Establishment Inspection Report ("EIR") conducted by the FDA in 2006 found that the post market survey validation process of the device was incomplete and failed to include all the data from the physicians surveyed during this time.

30. Whether intentionally or negligently, Defendants failed to properly conduct and monitor their own post market design validation physician surveys including those which demonstrated unfavorable or "dissatisfied" results.

31. These complaints and concerns of the physician surveyors were actively concealed by Defendants from Plaintiff, Plaintiff's surgeons, the FDA, members of the Class and the public at large.

32. During the 2006 EIR, corporate executives informed the FDA that the spring and summer period of 2005 showed a marketed increase in the number of complaints with the Composix Kugel Mesh Patch.

33. In spite of their knowledge of increasing complaints and complications, Defendants waited until August 30, 2005 to initiate a partial Composix Kugel Mesh Patch

distribution hold.

34. Even though Defendants realized the need for this distribution hold, they actively and intentionally chose not to immediately inform Plaintiff, Plaintiff's physicians, members of the Class, the FDA, and all other individuals who had been implanted or would be implanted with Composix Kugel Mesh Patches of the problems and/or defects.

35. Defendants have since admitted that the product quality hold and release procedure was not applied on a timely basis.

36. As a result of this dangerous and defective condition, and the numerous serious injuries that have resulted, the FDA issued Class 1 recalls of the X-Large Oval, Large Oval and Large Circle varieties of the Composix Kugel Mesh Patch. A Class 1 recall is the highest level of recall available to the FDA. It is issued when the FDA believes a medical product is dangerous or defective and predictably could cause serious health problems or death.

37. On December 22, 2005 and January 13, 2006, Davol and Bard announced the recall of the Composix Kugel Mesh X-Large patch. Subsequently, in March of 2006, the Defendants announced the recall of the Composix Kugel Mesh Large Patch as well.

38. Under these FDA recalls, the following products were subject to recall:

PC#0010206	Bard Composix Kugel	Extra Large Oval	8.7" x 10.7"
PC#0010207	Bard Composix Kugel	Extra Large Oval	10.8" x 13.7"
PC#0010208	Bard Composix Kugel	Extra Large Oval	7.7" x 9.7"
PC#0010209	Bard Composix Kugel	Large Oval	6.3" x 12.3"
PC#0010202	Bard Composix Kugel	Large Oval	5.4" x 7"
PC#0010204	Bard Composix Kugel	Large Circle	4.5"

39. Then, on January 10, 2007, Davol and Bard expanded the recall to include all

Composix Kugel Mesh Large Oval and Large Circle Mesh patches, as well as all products manufactured from January 2004 to January 2006, that had the same component design as the recalled manufacturing lots.

40. Upon information and belief, it is possible that additional Composix Kugel Mesh Patches will experience the same defects as the currently recalled models and will need to be recalled as well.

41. The FDA conducted the aforementioned EIR investigations in January and February of 2006. Upon information and belief, the results of these investigations determined, among other things, that Defendants:

a. had excluded ring failure events which should have been included from their complication database, reports, and recall notices;

b. misidentified numerous Composix Kugel Mesh Patch complication events;

c. failed to apply the product quality hold and release procedure on a timely basis;

d. failed to properly follow the procedures for conducting design validation review;

e. failed to identify all the actions necessary to correct and prevent the recurrence of further ring break and Composix Kugel Mesh Patch complications; specifically, they provided no justification for including only the Extra Large Composix Kugel Mesh Patch sizes in the December 2005 recall;

f. failed to provide full information which they knew regarding numerous Composix Kugel Mesh Patch complaints;

g. failed to actually perform strength testing on memory recoil rings for all sizes of Composix Kugel Mesh Patch before putting them into the stream of commerce;

h. failed to maintain appropriate sources for quality data to identify, track, and trend existing and potential causes for the ring failures and Composix Kugel Mesh Patch complaints resulting in numerous inconsistencies and

errors in the raw data and from the actual complaints and what was placed in the electronic databases;

i. failed to establish and implement procedures to ensure that the device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality System regulation; and

j. failed to ensure that devices conform to defined user/patient needs and intended uses.

42. Additionally, upon information and belief, the ring break issue with the Composix Kugel Mesh Patch was not brought to the FDA's attention until over *20 months* after Defendants knew of the first death resulting from their products.

43. Despite the serious risk of injury (and even death) resulting from the Composix Kugel Mesh Patch, Defendants took woefully insufficient steps to notify Plaintiff and the Class of the patches' defects.

44. Evidence shows that Defendants held back on implementing a full recall – and actively notifying patients of the recall – until over a year after the first recall was issued. In fact, evidence shows that for a period of time after the recall was issued Defendants informed doctors that because this was a "voluntary" recall, patients need not be notified at all.

45. Upon information and belief, Defendants claimed during their expanded recall that there had only been 28 reported ring breaks. Many of which were years before the first recall. In actuality, at least 85 ring breaks had been reported. Defendants only told the FDA about the ring breaks which they confirmed by getting the samples returned. Upon information and belief, if the sample was not returned, Defendants minimized the seriousness of the report and intentionally chose not to include the complaint when providing their statistical analysis to the FDA.

46. Upon information and belief, as of January 2007, roughly 100,000 Composix Kugel Mesh Patches had been sold. Upon information and belief, the vast majority of the patches which have been implanted are currently still inside patients residing in the United States.

GENERAL ALLEGATIONS

47. The Composix Kugel Mesh Patches present and constitute an unreasonable risk of danger and injury in the following respects:

a. the memory recoil ring of the Composix Kugel Mesh Patch is likely to malfunction during, or after, it is implanted;

b. the Composix Kugel Mesh Patch was not properly manufactured;

c. the Composix Kugel Mesh Patch was defectively designed;

d. the Composix Kugel Mesh Patch did not perform as safely as an ordinary consumer/patient would expect;

e. the Composix Kugel Mesh Patch was inadequate or insufficient to maintain its integrity during normal use after implantation in the consumer/patient; and/or

f. such further and additional defects as discovery and the evidence reveal.

48. At all times relevant, Defendants were engaged in the design, manufacturing, assembling, distributing, conveying and/or selling of the Composix Kugel Mesh Patch in their ordinary course of business. Defendants designed, manufactured, assembled and sold the devices to hospitals and physicians, knowing that they would be thereby sold to patients who needed hernia repair surgery, including Plaintiff and all other members of the Class.

49. Defendants' Composix Kugel Mesh Patches are uniformly defective because they possess the same potential for breakage or malfunction of the memory recoil ring and, as a result, are subject to risk of resulting injury.

50. At all times herein mentioned, Defendants knew, or in the exercise of reasonable care should have known, that the aforesaid products were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, were not suitable for the purpose they were intended and were unreasonably likely to injure the products' users.

51. Defendants did not have adequate and appropriate systems in place, or did not apply those systems, to collect and analyze any of the complaints they received from doctors, hospitals, and/or patients concerning the Composix Kugel Mesh Hernia Patches, as required by the U.S. Food & Drug Administration ("FDA"), thus leading to inconsistencies and irregularities in the way Defendants kept track of complaints they received regarding the failure of the Composix Kugel Mesh Patches.

52. At all times herein mentioned, Defendants knew, or in the exercise of reasonable care should have known, of the seriousness of the risk of using the Composix Kugel Mesh Patch based upon the state of knowledge of the patch as it existed at the time, and upon generally accepted medical and research standards and principles.

53. Upon information and belief, Defendants failed to send the necessary product failure reports to the FDA, indicating that the Composix Kugel Mesh Patch was causing serious and fatal injuries in persons who used the patch.

54. Upon information and belief, Defendants misrepresented the known risks inherent in the use of the Composix Kugel Mesh Patch.

55. Defendants did not timely apprise Plaintiff, members of the Class, the FDA, physicians and general public of the defect in their Composix Kugel Mesh Patches, despite Defendants' knowledge that memory recoil rings had failed due to the described defects.

Defendants' concealment of a known defect from Plaintiff and Class members equitably tolls any applicable statutes of limitation.

56. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of the Plaintiff and the members of the Class.

57. Upon information and belief, the purpose of Defendants' conduct, directed at patients, physicians and consumers, was to create demand for and sell the Composix Kugel Mesh Patches. Each aspect of Defendants' conduct combined to artificially create sales of the Composix Kugel Mesh Patches.

58. As a direct and proximate cause of cumulative and indivisible nature of Defendants' conduct and the recalled Composix Kugel Mesh Patches, Plaintiff and the Class members have suffered injuries and will require continual medical monitoring and care. Accordingly, Plaintiff and the Class have incurred and will continue to incur damages related to the recalled Composix Kugel Mesh Patches.

NAMED PLAINTIFF'S EXPERIENCE

59. Cory underwent a hernia repair surgical procedure on July 20, 2004 at Brigham & Women's Hospital located in Boston, Massachusetts, and, during the course thereof, Cory's physician implanted an Extra Large Oval Composix Kugel Mesh Patch (0010208) into his body.

60. The Composix Kugel Mesh Patch implanted in Cory was designed, manufactured, sold and distributed by Defendants, and was intended to be used by surgeons for hernia repair surgeries. Defendants represented these Composix Kugel Mesh Patches to be appropriate and suitable products for such purposes.

61. The Composix Kugel Mesh Patch in Cory's body presents a serious ongoing health risk due to its defective design and/or manufacture.

62. As a direct and proximate result of Defendants' defective design, manufacture, function and/or inadequate warnings regarding the Composix Kugel Mesh Patch, Cory has sustained, and will continue to sustain, injuries and damages, including, but not limited to, medical monitoring by means of increased physician follow-ups, non-invasive medical imaging and screening (such as CT scans, sonograms, and/or ultrasounds), and potential future invasive surgical and exploratory treatments.

CLASS ACTION ALLEGATIONS

63. Plaintiff brings this class action on behalf of himself and on behalf of all others similarly situated, as members of a proposed Massachusetts plaintiff class (the "Class") defined as follows:

> All citizens, residents or domiciliaries of the State of Massachusetts who have had a Composix Kugel Mesh Patch implanted into their person, which has not been explanted, and who have not previously filed a claim or lawsuit for personal injury, but will require medical monitoring.

This action is brought and may properly be maintained as a class action pursuant to the provisions of Rule 23(a)(1)-(4), 23(b)(2), and 23(b)(3). This action satisfies the numerosity, commonality, typicality, adequacy, predominance and superiority requirements of Rule 23.

64. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint. Specifically excluded from the proposed Class are Defendants, their officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint venturers, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with

Defendants and/or their officers and/or directors, or any of them; the Judge assigned to this action, and any member of the Judge's immediate family.

65. The Class is so numerous that the individual joinder of all its members is impracticable. As set forth above, the number of class members is at least several hundred.

66. Common questions of fact and law exist as to all members of the Class which predominate over any questions affecting only individual members of the Class. These common legal and factual questions, which do not vary from Class member to Class member, and which may be determined without reference to the individual circumstances of any Class member, include, but are not limited to, the following:

a. whether there are design and/or manufacturing defects in the Composix Kugel Mesh Patch;

b. whether Defendants failed to investigate the possible defects or safety concerns of the Composix Kugel Mesh Patch shown in reports and/or studies;

c. whether Defendants failed to follow FDA good manufacturing practices, failed to properly investigate manifestations of the Composix Kugel Mesh Patch over the past several years, failed to adequately document reports of the defect, and failed to exercise adequate quality control and testing;

d. whether Defendants' conduct in designing, manufacturing, marketing and monitoring the Composix Kugel Mesh Patch fell below the duty of care owed by Defendants to Plaintiff and Class members;

e. whether Defendants intentionally, knowingly, carelessly, recklessly, or negligently concealed information regarding the existence of a defect or safety concern in the Composix Kugel Mesh Patch from the FDA, physicians, Plaintiff and members of the Class;

f. whether Composix Kugel Mesh Patches share a common and inherent design defect that causes them to break, creating a risk of injury or death to patients in whom they were implanted;

g. whether Defendants negligently, recklessly, or intentionally misrepresented the quality and usefulness of the Composix Kugel Mesh Patch;

h. whether Defendants are liable for selling a dangerously defective product;

i. whether the Class have been injured by virtue of the Defendants' deceptive business practices and conduct;

j. whether Defendants are strictly liable in tort for selling a dangerously defective product;

k. whether persons implanted with the Composix Kugel Mesh Patch are at increased risk of developing serious latent injury;

l. whether there exists monitoring and testing procedures which make early detection and treatment of serious injury caused by exposure to the Composix Kugel Mesh Patch possible and beneficial;

m. whether the Class is entitled to compensatory damages, and if so, the nature and extent of such damages;

n. whether the Class is entitled to medical monitoring and treatment, at Defendants' expense; and

o. whether Defendants are liable for punitive or exemplary damages, and if so, the amount necessary and appropriate to punish Defendants for their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary damages.

67. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and the members of the Class have suffered similar injury and are facing further damages arising out of Defendants' common course of conduct, as alleged herein. The damages of each Class member were and are caused directly by Defendants' conduct, as alleged herein. Plaintiff and the members of the Class must prove the same facts in order to establish the same claims, as described herein, which apply to all Class members.

68. Plaintiff is an adequate representative of the Class because he has been billed for the Composix Kugel Mesh Patch and medical costs relating to such devices, and will continue to incur related medical expenses, and his interests do not conflict with the interests of the members of the Class he seeks to represent. Plaintiff has retained experienced and competent counsel, and

together Plaintiff and counsel intend to prosecute this action vigorously for the benefit of the Class. The interests of the Class members will fairly and adequately be protected by Plaintiff and his counsel.

69. A class action is superior to other available methods for the fair and efficient adjudication of this litigation because individual litigation of the claims of all Class members is impracticable. Even if every Class member could afford individual litigation, the court system could not. It would be unduly burdensome to the courts in which individual litigation of thousands of cases would proceed. Individual litigation presents a potential for inconsistent or contradictory judgments, and the prospect of a race for the courthouse, and an inequitable allocation of recovery among those with equally meritorious claims. Individual litigation increases the expense and delay to all parties and the court system in resolving the legal and factual issues common to all Composix Kugel Mesh Patch claims. By contrast, the Rule 23 class action device presents far fewer management difficulties and provides the benefit of a single adjudication, economies of scale, and comprehensive supervision by a single court.

70. The various claims asserted in this action are additionally or alternatively certifiable under the provisions of Rule 23(b)(I) and/or (b)(2) because:

a. the prosecution of separate actions by thousands of individual Class members would create a risk of inconsistent or varying adjudications with respect to individual Class members, thus establishing incompatible standards of conduct for Defendants;

b. the prosecution of separate actions by individual Class members would also create the risk of adjudication with respect to them that would, as a practical matter, be dispositive of the interests of the other Class members who are not a party to such adjudications and would substantially impair or impede the ability of such non-party Class members to protect their interests; and

c. Defendants have acted or refused to act on grounds generally applicable to the entire Class, thereby making appropriate final declaratory and

injunctive relief with respect to the Class as a whole.

71. Plaintiff and the Class are consumers of the defective product and were injured by Defendants' tortuous conduct.

72. Had the Defendants not engaged in the conduct described above, Plaintiff and members of the Class would not require medical monitoring of their condition.

73. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff and Class members for the Composix Kugel Mesh Patches and/or for the costs of replacing the Composix Kugel Mesh Patches that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

MEDICAL MONITORING ALLEGATIONS

74. Plaintiff re-alleges and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

75. Plaintiff and the Class have been significantly exposed to a hazardous product through the tortuous conduct of Defendants. Indeed, Plaintiff and the Class members have sustained a present injury in the form of a defective and dangerous medical device surgically implanted into their bodies.

76. As a direct and proximate result of that exposure, Plaintiff and the Class have suffered an increased risk of incurring serious latent injury relative to individuals who do not have Defendants' mesh product surgically implanted in their bodies. This increased risk of injury makes it reasonably necessary for Plaintiff and the Class to undergo periodic diagnostic medical examinations different from what would be prescribed in absence of the exposure to Defendants' defective device. As such, medical monitoring is necessary and reasonably certain to be incurred as a proximate result of Defendants' conduct.

77. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the Class have incurred and will likely continue to incur medical costs relating to the Composix Kugel Mesh Patch, including medical monitoring and/or other hospital costs, in an amount to be proven at trial. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the Class are entitled to relief in the form of a court supervised medical monitoring program.

78. Medical monitoring is medically reasonable and necessary in order to provide for the early detection and prevention of irreparable harm, sever and debilitating injuries and death. In the absence of such relief, Plaintiff and the Class members might not receive prompt medical care that could prolong their productive lives, increase prospects for improvement and minimize disability.

79. Effective and relatively cost effective medical testing and monitoring procedures are currently available, including but not limited to CT Scans, to determine whether any problems have developed due to the implanted mesh patch. Such medical monitoring will significantly decrease the risk of injury and death. In fact, upon information and belief, doctors and hospitals have already began creating an implementing their own medical monitoring programs – to address this real and dangerous problem.

COUNT I

(Negligence)

80. Plaintiff re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

81. At all times herein mentioned Defendants had a duty to exercise reasonable care in the course of its design, manufacture, sale, testing, marketing, advertising, promoting, distribution and warning about the Composix Kugel Mesh Patch. This duty included, among

other things, to assure that the products did not cause users to suffer from unreasonable and dangerous side-effects and to warn Plaintiff and Class members of the defective nature of Defendants' devices. Defendants breached their duty of reasonable care to Plaintiff and Class members by incorporating a defect into the design of the devices, thereby causing injuries to Plaintiff and Class members.

82. At all times herein mentioned Defendants had an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the recalled Composix Kugel Mesh Patch.

83. At all times relevant, Defendants knew, or in the exercise of reasonable care should have known, that the Composix Kugel Mesh Patches were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, and were unreasonably likely to injure the products' users.

84. Defendants so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the aforesaid products, that they were dangerous and unsafe for the use and purpose for which they were intended.

85. Defendants knew, or should have known, that consumers such as Plaintiff could foreseeably suffer injuries as a result of Defendants' failure to exercise ordinary care.

86. Defendants breached their duty of reasonable care to Plaintiff and Class members, including but not limited to the following negligent acts and/or omissions:

a. manufacturing, producing, promoting, formulating, creating and/or designing the Composix Kugel Mesh Patch without thoroughly and

adequately testing it;

b. failing to conduct sufficient testing programs to determine whether or not the aforesaid Composix Kugel Mesh Patch was safe for use; in that Defendants knew or should have known that the Composix Kugel Mesh Patch was unsafe and unfit for use by reason of the dangers to its users;

c. selling the Composix Kugel Mesh Patch without making proper and sufficient tests to determine the dangers to its users;

d. failing to adequately and correctly warn Plaintiff and Class members, the public, the medical and healthcare profession, and the FDA of the dangers of the Composix Kugel Mesh Patch;

e. failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and use the Composix Kugel Mesh Patch;

f. negligently advertising and recommending the use of the Composix Kugel Mesh Patch without sufficient knowledge as to its dangerous propensities;

g. negligently representing that the Composix Kugel Mesh Patch was safe for use for their intended purpose, when, in fact, it was unsafe;

h. negligently designing the Composix Kugel Mesh Patch in a manner which was dangerous to its users;

i. negligently manufacturing the Composix Kugel Mesh Patch in a manner which was dangerous to its users;

j. negligently producing the Composix Kugel Mesh Patch in a manner which was dangerous to its users;

k. negligently assembling the Composix Kugel Mesh Patch in a manner which was dangerous to its users;

l. improperly concealing information concerning FDA warnings from the Plaintiff and Class members, healthcare professionals, and/or the FDA in knowing that the Composix Kugel Mesh Patch was unsafe, dangerous, and/or non-conforming with FDA regulations.

m. violating statutes, rules and ordinates concerning the manufacturing, marketing, and/or testing of their product.

87. Defendants were negligent in the designing, researching, supplying, manufacture,

promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Composix Kugel Mesh Patch in that they:

a. failed to use due care in designing and manufacturing the Composix Kugel Mesh Patch so as to avoid the aforementioned risks to individuals when the Composix Kugel Mesh Patch was used to repair ventral and incisional hernias;

b. failed to accompany their product with proper and/or accurate warnings regarding all possible adverse risks and side effects associated with the use of the Composix Kugel Mesh Patch;

c. failed to accompany their product with proper warnings regarding all possible adverse risks and side effects concerning the failure and/or malfunction of the Composix Kugel Mesh Patch;

d. failed to warn Plaintiff and Class members of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

e. failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Composix Kugel Mesh Patch;

f. failed to warn Plaintiff and Class members prior to actively encouraging the sale of the Composix Kugel Mesh Patch, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and/or

g. were otherwise careless or negligent.

88. Defendants breached their duty of reasonable care to Plaintiff and Class members by failing to exercise due care under the circumstances.

89. As a direct and proximate result of the carelessness and negligence of Defendants, as set forth in the preceding paragraphs, Plaintiff and Class members have sustained and will continue to sustain damages, and are therefore entitled to relief according to proof.

90. As a direct and proximate result of Defendants' actions, Plaintiff and members of the Class have already suffered damages – including the purchase and implantation of defective

and dangerous medical devices – and the will be required to pay sums to ascertain the existence, nature and extent of their injuries in the future.

91. For the reasons stated above, Defendants are liable, jointly and severably, to Plaintiff and every Class Member for relief including periodic medical monitoring.

COUNT II

(Breach of Implied Warranty of Merchantability)

92. Plaintiff re-alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

93. Defendants are liable to Plaintiff for their breach of implied warranty of merchantability in the following respect:

a. Defendants designed, manufactured, distributed, and/or sold the Composix Kugel Mesh Patches which were implanted in Plaintiff. Defendants impliedly warranted to Plaintiff, his physicians and health care providers, that the Composix Kugel Mesh Patches were of merchantable quality and safe for the use for which they were intended.

b. The Composix Kugel Mesh Patch is designed or manufactured in an unsafe and unreasonably dangerous way. This condition is a result of inadequate or faulty testing, designing, developing, manufacturing, promoting, distributing, and/or sale of the Composix Kugel Mesh Patch.

c. Defendants knew or should have known that the Composix Kugel Mesh Patches at the time of sale was intended to be used for the purpose of surgically implanting them into the body for hernia repair.

94. When the Composix Kugel Mesh Patch was distributed into the stream of commerce and sold by Defendants, they were unsafe for their intended use, and not of merchantable quality, as warranted by Defendants in that they had very dangerous propensities when used as intended and implanted into a patient's body where they could cause serious injury of harm or death to the end user.

95. Plaintiff is a hernia repair surgery patient who had the Composix Kugel Mesh

Patch surgically implanted into his body. As such, Defendants expected, or reasonably should have expected, Plaintiff to use or be affected by the medical device.

96. As a direct and proximate result of Defendants' conduct and breach of their implied warranty, Plaintiff now requires medical monitoring.

COUNT III

(Breach of Express Warranty)

97. Plaintiff re-allege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

98. Defendants' concealment and failure to warn through promotional statements and product literature expressly warranted that the Composix Kugel Mesh Patch was safe and/or well accepted by users.

99. The Composix Kugel Mesh Patch does not conform to these express representations because the Composix Kugel Mesh Patch is not safe and have numerous serious risks and side effects.

100. Defendants breached the aforesaid express warranties, as their Composix Kugel Mesh Patches were defective.

101. Defendants expressly represented to the users, their physicians, healthcare providers, and the FDA that the Composix Kugel Mesh Patch was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

102. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Composix Kugel Mesh Patch was not safe and fit for the use intended, and, in fact, produced serious injuries to the users.

103. As a direct and proximate result of the breach of said warranties, Plaintiff and Plaintiff Class members suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

104. Defendants expected, or reasonably should have expected, members of the medical community, including physicians and/or other healthcare professionals, to rely upon the representations and warranties of the Defendants for use of the Composix Kugel Mesh Patch.

105. As a result of the defective nature of the Composix Kugel Mesh Patch, those persons who received the Composix Kugel Mesh Patch are at an increased risk of suffering serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, and such other side effects as serious infection. They also face the need for additional surgery to remove or replace the defective product, the need for subsequent surgery to repair perforations caused by the defective product, as well as other severe and permanent health consequences as a result of the defective, unsafe and recalled product they received.

106. As a result of the foregoing acts and omissions, the Plaintiff and Class members have suffered damages and will require health care and services and will incur medical, health, incidental and related expenses now or in the future.

COUNT IV

(Breach of Implied Warranty)

107. Plaintiff re-alleges and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

108. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold the

Composix Kugel Mesh Patch, which is used for repairing ventral and incisional hernias.

109. At the time Defendants marketed, sold, and distributed the Composix Kugel Mesh Patch for use by Plaintiff and Class members, Defendants knew of the use for which the Composix Kugel Mesh Patch was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

110. Defendants impliedly represented and warranted to the users and their physicians, healthcare providers, and the FDA that the Composix Kugel Mesh Patch was safe and of merchantable quality, and fit for the ordinary purpose for which said product was to be used.

111. That said representations and warranties aforementioned were false, misleading, and inaccurate in that the Composix Kugel Mesh Patch was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

112. The Composix Kugel Mesh Patch was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

113. Defendants breached the aforesaid implied warranties, as their Composix Kugel Mesh Patch were not fit for their intended purposes and uses. Plaintiff and the Class members are hernia repair surgery patients who had the Composix Kugel Mesh Patch surgically implanted in their bodies. As such, Defendants expected, or reasonably should have expected, Plaintiff and the Class members to use or be affected by the medical device.

114. As a result of the defective nature of the Composix Kugel Mesh Patch, those persons who received the Composix Kugel Mesh Patch are at an increased risk of suffering serious and dangerous side effects, including but not limited to bowel perforations, bowel

obstructions, chronic intestinal fistulae, death, and such other side effects as serious infection. They also face the need for additional surgery to remove or replace the defective product, the need for subsequent surgery to repair perforations caused by the defective product, as well as other severe and permanent health consequences as a result of the defective, unsafe and recalled product they received.

115. As a result of the foregoing acts and omissions, the Plaintiff and the Class members have suffered damages and will require health care and services and will incur medical, health, incidental and related expenses now or in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly situated, prays for judgment against Defendants as follows:

1. For an Order certifying the Class and any appropriate subclasses thereof under the appropriate provisions of Rule 23, and appointing Plaintiff and his counsel to represent the Class;

2. For an Order establishing a medical monitoring program, funded by Defendants, to provide medical testing, screening, services, research and education and a medical/legal registry to ensure that the Class members receive prompt and proper medical treatment;

3. For an award of attorneys' fees and costs;

4. For an award of treble or punitive damages;

5. For prejudgment interest; and

6. For such other and further relief as this court may deem just and proper.

JURY DEMAND

Plaintiff on behalf of himself and all others similarly situated, hereby demands a trial by jury in this case.

Dated: November 4, 2009

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